K020774

MAY 22 2002

Premarket Notification 510(k) IMAGINE h.e. Press Design-Ceramic

510 (k) Summary

Device description

IMAGINE h.e. Press Design-Ceramic is a dental porcelain system, which provides an easy to use and aesthetically pleasing material to fabricate metal-free, all-ceramic dental restorations. It consists of pre-shaded ceramic ingots, which had to be processed in a ceramic press furnace by the dental technicians.

According to ISO 6872, IMAGINE h.e. Press Design-Ceramic is a Type 2, Class 1 dental ceramic, which meets the demands of this standard and even exceeds most given limits.

IMAGINE h.e. Press Design-Ceramic can be used for manufacturing metal-free all-ceramic single unit restorations in the anterior region and posterior region up to the second premolar, O-, MO- or MOD- inlays, onlays, and veneers.

The Coefficient of Thermal Expansion (CTE) of IMAGINE h.e. Press Design-Ceramic pellets were designed to be exactly compatible with the Coefficient of Thermal Expansion of IMAGINE h.e. Ceramic. Therefore IMAGINE h.e. Ceramic should be used exclusively for the layering or staining techniques.

IMAGINE h.e. Press Design-Ceramic is market and clinically applicated in Europe, particularly in Germany, since February, 2001.

The IMAGINE h.e. Press Design-Ceramic assortment consists of the following ingots (pellets):

Type of the Pellet	Amount	Shades
Pellets Naturescence [N]	16 different shades	[NA1] [NA2] [NA3] [NA3,5] [NA4] [NB1] [NB2] [NB3] [NB4] [NC1] [NC2] [NC3] [NC4] [ND2] [ND3] [ND4]
Pellets Basic	16 different shades	[A1] [A2] [A3] [A3,5] [A4] [B1] [B2] [B3] [B4] [C1] [C2] [C3] [C4] [D2] [D3] [D4]
Pellets Naturescence Bleaching [NBL]	4 different shades	[NBL A01] [NBL A02] [NBL B01] [NBL B02]
Pellets Basic Bleaching [BL]	4 different shades	[BL A01] [BL A02] [BL B01] [BL B02]
Transparency Pellets Staining Technique [MT]	11 different shades	[MT01] [MT02] [MT 1] [MT 2] [MTC0] [MTC1] [MTC2] [MTC3] [MTC4] [MTC5] [MTweiß]
Intensive, opaceous Dentine pellets [IoD]	4 different shades	[ioD A] [ioD B] [ioD C] [ioD D]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2002

Mr. Gerhard Polzer
Director, Regulatory Affairs
Wieland Dental + Technik GmbH & Company
Schwenninger Strabe 13
Forzheim,
GERMANY D-75179

Re: K020774
Trade/Device Name: IMAGINE h.e. Press Design-Ceramic
Regulation Number: 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: March 8, 2002
Received: March 11, 202

Dear Mr. Gerhard Polzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020774

4. Statement of indication for use

IMAGINE h.e. Press Design-Ceramic is a dental porcelain that can be used by dental technicians for the fabrication of metal free all-ceramic dental restorations.

IMAGINE h.e. Press Design-Ceramic is intended for manufacturing:

- Metall-free single unit restorations in the anterior region and posterior region up to the second premolar,
- O, MO, or MOD inlays and
- Onlays, and veneers

The official form for the "Indication for Use Statement" developed by the Office of Device Evaluation is given as Annex K

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020774